REMARKS

Favorable reconsideration and allowance of the present application are respectfully requested in view of the following remarks.

Claims 1-6, 9-13, and 39-45 are pending in the present application including independent claim 1. As indicated above, the limitations of previous dependent claim 8 have now been incorporated into independent claim 1. Thus, independent claim 1, now requires that a polyelectrolyte is immobilized within the compensation zone that has a net charge opposite to that of the detection probes. The polyelectrolyte is configured to bind to the conjugated detection probes and complexes formed between the analyte and the conjugated detection probes passing through the detection zone to generate a compensation signal having an intensity. Furthermore, independent claim 1 has also been amended to require that the calibration zone is positioned between the detection zone and the compensation zone.

In the Office Action, previous dependent claim 8 (now incorporated into independent claim 1) was rejected under *35 U.S.C. § 103(a)* as being obvious over U.S. Patent Application Publication No. 2006/0008921 to Daniels, et al. in view of U.S. Patent No. 5,670,381 to Jou, et al. Daniels, et al. is directed to an immunochromatographic assay test strip that employs semiconductor nanocrystals as a detectable label. More specifically, the test strip includes a first detection reagent that is a conjugate of a ligand and a semiconductor nanocrystal. When combined with the test sample, the ligand binds with the analyte to form a detection complex. The detection complex then migrates to and binds with a capture ligand to form an immobilized capture complex. The test strip may also include a control ligand that is capable of

specifically binding to detection reagent that is unbound to the analyte. ¶ [0117]. For example, suitable control ligands are said to include antibodies, antibody fragments, etc. ¶ [0184]. Daniels, et al., however, fails to disclose various aspects of independent claim 1. For instance, as correctly noted by the Examiner, Daniels, et al. fails to disclose a compensation zone that includes a polyelectrolyte having a net charge opposite to that of the conjugated detection probes.

Nevertheless, the Office Action combined Daniels, et al. with Jou, et al. in an attempt to render obvious independent claim 1. Jou, et al. describes a porous material containing (a) a first reagent zone containing a diffusive indicator (first binding member and label); (b) second reagent containing a diffusive capture reagent (second binding member and first charged substance); and (c) reaction zone containing an immobilized charged substance that has an opposite charge to the first charged substance. In Example 1, for instance, the assay employs an alkaline phosphate-labeled anti-CEA antibody (indicator reagent); an anti-CEA/polyglutanic acid conjugate (capture reagent); and a solid phase coated with Celquat® L-200. With the addition of CEA, complexes form between the indicator reagent, CEA, and capture reagent.

As an initial matter, the systems of Daniel, et al. and Jou, et al. are so vastly different from each other that one of ordinary skill in the art would not have possibly found it obvious to make the combination proposed in the Office Action. Even if Jou, et al. is combined with Daniels, et al., however, the resulting combination still fails to disclose each limitation of the present claims. For example, as with most conventional immunoassays, detection is accomplished in Jou, et al. through complexes formed between the analyte (CEA), the binding member of the indicator reagent (anti-CEA),

and the binding member of the capture reagent (anti-CEA). The charged substances are used only to enhance the immobilized of these complexes on the solid phase (e.g., porous material), but not as the primary binding mechanism for detection of the analyte. Thus, conjugation of the charged substance of Jou, et al. to the "control ligand" of Daniels, et al. would not lead to the generation of the "compensation signal" as claimed.[1] That is, the signal generated at the control line in Daniels, et al. would still stem primarily from the specific binding between the biological control ligand and the biological reagent (antibody) conjugated to the nanocrystals. Of course, the combination fails to disclose other limitations of the present claims. For instance, independent claim 1 also requires that the calibration zone is positioned between the detection and compensation zones. In this manner, any risk that the calibration probes would be inadvertently captured by the polyelectrolyte within the compensation zone is minimized. Neither of the references fails to disclose this feature.

Thus, for at least the reasons indicated above, Applicants respectfully submit that the present claims patentably define over the cited references, taken singularly or in any proper combination. Applicants emphasize that an invention is not obvious simply because various parts of the claims may be found somewhere in the prior art. If this were the case, virtually every invention would be considered obvious. Instead, the proper standard under *§ 103* is whether the claimed invention *as a whole* when viewing the teachings of the references *in their entirety*. In this case, as explained above, the present claims are so substantially different from the references, when properly viewed

[1] To even better clarify this distinction, Applicants have added new dependent claim 43, which further requires that the compensation zone is generally free of biological capture reagents.

in their entirety, that one of ordinary skill in the art would not have conceivably modified and/or combined the references as suggested in the Office Action.

It is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner DiRamio is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully requested,

DORITY & MANNING, P.A.

5/12/08
Date

Jason W. Johnston
Registration No. 45,675
P.O. Box 1449
Greenville, SC 29602-1449
Telephone: (864) 271-1592
Facsimile: (864) 233-7342